

CERTIFICATE OF MAILING

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ELI LILLY AND COMPANY

By RP Rhodes

Date 12-23-97

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Brader, et al.)
)
Serial No. : 08/484,542)
) Group Art Unit:
Filed : 7 June 1995) 1813
)
For : Stabilized Acylated Insulin)
Formulations) Examiner:
) Allen,
Docket No. : X-10097)

DECLARATION UNDER 37 C.F.R. §1.131

Assistant Commissioner for Patents

Washington, D. C. 20231

Sir:

We, Mark L. Brader and Michael J. Beckage, declare that:

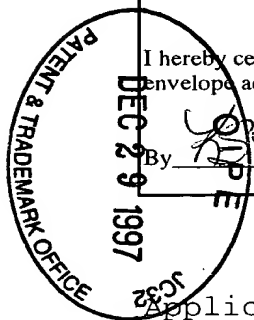
We are co-inventors and applicants in this application.

Attached exhibits 1, 2, and 3 are copies of pages from Michael J. Beckage's notebook in which he recorded the preparation of a formulation comprising an aqueous solution of a fatty acid-acylated insulin and approximately 0.35 mole of zinc per mole of said fatty acid-acylated insulin, and having a pH of approximately 7.5. The fatty-acid acylated insulin was N^ε-Lys^{B29}-palmitoyl-human insulin, which is referred to as C16-insulin. The formulation also contained *m*-cresol, a phenolic compound, at a concentration of approximately 2.5 mg/mL. The dates have been redacted.

All the actions, events, and observations described in exhibits 1, 2, and 3 occurred in the United States, prior to 23 March 1995.

We further declare that all statements made herein of our own knowledge are true, that all statements made on information and belief are believed to be true, and that these

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Serial No. 08/484,542

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statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both (18 U.S.C. 1001), and may jeopardize the validity of the application or any patent issuing thereon.

11/5/97
Date

11/5/97
Date

Mark L. Braden
Mark L. Braden

Michael J. Beckage
Michael J. Beckage

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